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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,680	07/01/2004	Wei Wang	MSB-7293	3098

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EXAMINER	
HA, JULIE	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
11/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/500,680	WANG ET AL.	
	Examiner	Art Unit	
	JULIE HA	1654	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 October 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *22 October 2009*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: See *Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Continuation of 11.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Julie Ha/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654

Continuation of 3. NOTE: The amendment filed on October 22, 2009 raises new issue that is inconsistent with the disclosure at paragraph [0050] and [0055] of instant specification for example. The amendment recites, "wherein said formulation is free of additional active components". However, at paragraphs [0050] and [0055] the specification discloses that the formulation containing PACAP 66 may be used alone or in combination with additional therapies and/or compounds known to those skilled..." (see paragraph [0055]). Therefore, the amendment is inconsistent with the instant disclosure.

Continuation of 11:

Claims 1, 3, 34-35 and 40 remain rejected under 35 U.S.C. 102(e) as being anticipated by Edmondson et al (US Patent No. 7,125,873), as set forth in the previous office action.

Applicant argues that "claim 1 and dependent claim 3, are drawn to a stabilized peptide formulation concisting essentially of the peptide PAP 66 or a salt thereof, a zinc salt, and a pharmaceutically acceptable organic solvent...and where the formulation is free of additional active components." Applicant argues that "the formulation comprising Compound I as taught by Edmonson et al teaches a pharmaceutical composition that comprises two active agnets, a compound of Formula I and at least one of PACAP, PACAP mimetics, and PACAP receptor 3 agonists."

Applicant's arguments have been fully considered but have not been found persuasive, because the amendment to the claims is not consistent with the disclosure in the instant specification. As described above, paragraphs [0050] and [0055] of instant specification disclose that the formulation containing PACAP 66 may be used alone or in combination with additional therapies and/or coponds known to theose skilled...Since the claim recites, "consisting essentially of" and consisting essentially of occupies the middle gound between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising format...for the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to comprising (see MPEP 2105). Therefore, the rejection is maintained.

Claim 11 remains rejected under 35 U.S.C. 103(a) as being unpatentalbe over Edmondson et al (US Patent No. 7,125,873), as set forth in the previous office action.

Applicant argues that "claim 1, as newly amended, is drawn to a stabilized peptide formulation, either in a solution or in a suspension, consisting essentially of...Applicant has reduced the scope of the claims by newly adding the limitation that recited formulation is free of additional active components." Applicant argues that "Edmondson et al exceeds the scope of the instant claims, and does not teach all the limitations of the claims as newly amended."

Applicant's arguments have been fully considered, but have not been found persuasive, because the amendment to the claims is not consistent with the disclosure in the instant specification, as described supra. Therefore, the rejection is maintained.

Claims 44-46 and 48-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oshaki et al (US Patent No. 5,428,129) in view of Thakur (US 2003/129133A1) and Edmondson et al (US Patent No. 7,125,873), as set forth in the previous office action.

Applicant argues that the claims have been cancelled and the rejection is moot.

Applicant's arguments have been fully considered but have not been found persuasive, because the amendment to the claims have not been entered. The rejection is maintained.

Claims 1, 3, 8, 10-13, 15-20, 22, 26, 29-30, 34-37 and 40 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Edmondson et al (US Patent No. 7,125,873) in view of Pallenberg et al (US Patent No. 5,538,945) and Maccecchini (US Patent No. 5,830,998) and Bolin (US Patent No. 5,234,907) and Igari (US 2003/0058622 A1), as set forth in the previous office action.

Applicant argues that claims 11-13 have been cancelled and "claim 1 and dependent claim 3, 8, 10, 15 and 16, as newly amended, are drawn to a stabilized peptide formulation consisting essentially of the peptide PAP 66 or a salt thereof, a zinc salt, and a phamaceutically acceptable organic solvent, where the zinc salt is ZnCl2, and where the formulation is free of additional active components...Claim 17 and dependent claims 18, 19 and 20 are drawn to a stabilized peptide formulation...wherein said formulation is free of additional active components...Claim 26 and dependent claims 29 and 30 are drawn to a stabilized peptide formulation...wherein said formulation is free of additional active components...Claim 34 and dependent claims 35-37 and 40 are drawn to a stabilized dried mixture consisting essentially of ZnCl2 and the peptide PAP 66 or salt thereof, and where the formulation is free of additional components." Applicant argues that "Edmondson et al does not fall under the scope of the instant claims as newly amended. Edmondson et al does not teach a dried formulation as required by independent claims 17, 26 and 34." Applicant argues that "Pallenberg teaching that peptide-copper complexes formulated for administration may contain DMSO, Maccecchini's teaching of a peptide fomrulation comprising an organic solvent and a transition metal, Bolin's teaching of organic solvents, TFA, HLC and lyophilization, and Igari's teaching of water insoluble, polyvalent metal salt of a water soluble substrate, do not teach these missing limitations."

Applicant's arguments have been fully considered but have not been found persuasive, because the amendment to the claims is not consistent with the disclosure in the instant specification, as described supra. Furthermore, as described in the preivous office action, it would have been obvious to one of ordinary skill in the art to combine the teachings of Edmondson, Pallenberg, Maccecchini, Bolin and Igari to formulate a stabilized peptide formulatioin in DMSO and transition metal salts, since they teach stabilized peptide formulation. One of ordinary skill in the art would be motivated to add in DMSO as organic solvent, since DMSO is a penetration enhancement agent that are used in topical and injection formulations. THere is a reasonable expectation of success, since Edmondson et al teach the formulation

if 1,3-butane diol, and DMSO is readily available solvent that is used to enhance penetration and is safe for topical and injection usage (pharmaceutically acceptable). Furthermore, it would have been obvious to one of ordinary skill in the art to use pharmaceuticlaly acceptable organic or inorganic salts in the formulation to produce a stabilized peptide formulation. One of ordinary skill in the art would have been motivated to use $ZnCl_2$, since it is a pharmaceutically acceptable salt that is used in pharmaceutical compositions that are in an injectable or oleaginous suspension. Furthermore, Edmondson reference and Igari reference teach zinc and copper transition metal salts, thus one would try one for the other. Therefore, the rejection is maintained.